



Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® palpable breast masses.

BIBLIOGRAPHIC SOURCE(S)

Parikh JR, Bassett LW, Mahoney MC, Bailey L, Birdwell RL, Burnside ES, D'Orsi CJ, Harvey JA, Kaplan SS, Newell MS, Rabinovitch R, Rosen EL, Sutherland ML, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 10 p. [42 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Parikh JR, Evans WP, Bassett L, Berg WA, D'Orsi C, Farria DM, Herman CR, Kaplan SS, Liberman L, Mendelson E, Edge SB, Expert Panel on Women's Imaging - Breast. Palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 4 p. [30 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Palpable breast mass

- Breast cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for patients with palpable breast masses

TARGET POPULATION

Women with palpable breast masses

INTERVENTIONS AND PRACTICES CONSIDERED

1. Mammography
2. Ultrasound
3. Core biopsy
4. Fine needle aspiration
5. Magnetic resonance imaging
6. Positron emission tomography

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in the evaluation and diagnosis of a palpable breast mass

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the American College of Radiology (ACR) Appropriateness Criteria® Evidence Table Development document (see "Availability of Companion Documents" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Modified Delphi Technique

When the data available from existing scientific studies are insufficient, the American College of Radiology Appropriateness Criteria (ACR AC) employs systematic consensus techniques to determine appropriateness. The ACR AC panels use a modified Delphi technique to determine the rating for a specific procedure. A series of surveys are conducted to elicit each individual panelist's expert opinion of the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario based on the available data. ACR staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. Voting surveys are completed by panelists without consulting other panelists. The ratings are integers on a scale between 1 and 9, where 1 means the panel member feels the procedure is "least appropriate" and 9 means the panel member feels the procedure is "most appropriate." Each panel member has one vote per round to assign a rating. The surveys are collected and de-identified and the results are tabulated and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without

excessive bias from fellow panelists in a simple, standardized, and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. If eighty percent (80%) of the panel members agree on a single rating or one of two consecutive ratings, the final rating is determined by the rating that is closest to the median of all the ratings. Up to three voting rounds are conducted to achieve consensus.

If consensus is not reached through the modified Delphi technique, the panel is convened by conference call. The strengths and weaknesses of each imaging examination or procedure are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Palpable Breast Masses

Variant 1: Woman 30 years of age or older, initial evaluation.

Radiologic Procedure	Rating	Comments	RRL*
Mammography	9	Mammography should be done first	Low

Radiologic Procedure	Rating	Comments	RRL*
diagnostic		for patients in this age group. It may demonstrate additional findings of concern. Ultrasound should be used right after the mammogram. Ultrasound is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential.	
US breast	9	Ultrasound should be done right after the mammogram. Ultrasound is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential. In addition, ultrasound may be used to guide intervention, if needed.	None
MRI breast with contrast	1		None
PET breast	1		High
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 2: Woman 30 years of age or older, mammography findings suspicious for malignancy.

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	Mammography should be done first for patients in this age group. It may demonstrate additional findings of concern. Ultrasound should be used right after the mammogram. Ultrasound is critical to ensure that	None

Radiologic Procedure	Rating	Comments	RRL*
		the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential. In addition, ultrasound may be used to guide intervention, if needed.	
Core biopsy breast	9	Core biopsy should be performed after the diagnostic mammogram and ultrasound evaluation is complete.	NS
MRI breast with contrast	3		None
Fine needle aspiration breast	2		NS
PET breast	1		High
Mammography short interval follow-up	1		Low
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 3: Woman 30 years of age or older, mammography findings probably benign.

Radiologic Procedure	Rating	Comments	RRL*
US breast	9	Ultrasound is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging and clinical findings is essential.	None
Mammography short interval follow-up	7	Short-interval follow-up may be appropriate after workup with ultrasound.	Low
Core breast biopsy	5	Ultrasound is critical to ensure that the palpable finding corresponds to	NS

Radiologic Procedure	Rating	Comments	RRL*
		the mammogram finding. Concordance between the imaging findings and clinical findings is essential. The decision to biopsy may depend on the suspicion of clinical findings and ultrasound.	
Fine needle aspiration breast	3	Ultrasound is critical to ensure that the palpable finding corresponds to the mammogram finding. Concordance between the imaging findings and clinical findings is essential. The decision to biopsy may depend on how suspicious the clinical and ultrasound findings are.	NS
MRI breast with contrast	2		None
PET breast	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 4: Woman 30 years of age or older, mammography findings benign (like lipoma).

Radiologic Procedure	Rating	Comments	RRL*
US breast	7		None
Mammography short interval follow-up	2		Low
MRI breast with contrast	1		None
PET breast	1		High
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS

Radiologic Procedure	Rating	Comments	RRL*
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 5: Woman 30 years of age or older, mammography findings negative.

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		None
MRI breast with contrast	2		None
Fine needle aspiration breast	2		NS
Core biopsy breast	2		NS
Mammography short interval follow-up	1		Low
PET breast	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 6: Woman younger than 30 years of age, initial evaluation.

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		None
Mammography diagnostic	3	In high-risk patients younger than age 30, mammography may be used first.	Low
MRI breast with	2		None

Radiologic Procedure	Rating	Comments	RRL*
contrast			
PET breast	1		High
Fine needle aspiration breast	1		NS
Core biopsy breast	1		NS
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 7: Woman younger than 30 years of age, US findings suspicious for malignancy.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9	Bilateral diagnostic mammography should be performed immediately after the ultrasound to help characterize the mass and to evaluate for additional lesions that may be occult by ultrasound.	Low
Core biopsy breast	9	Core biopsy of the malignant palpable mass should only be done after bilateral diagnostic mammographic evaluation is complete.	NS
MRI breast with contrast	2		None
Fine needle aspiration breast	2		NS
US breast short interval follow-up	1		None
PET breast	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 8: Woman younger than 30 years of age, US findings probably benign.

Radiologic Procedure	Rating	Comments	RRL*
US breast short interval follow-up	8		None
Mammography diagnostic	5	Evidence is lacking. Variability in practice.	Low
Fine needle aspiration breast	3	Biopsy may be performed to alleviate patient anxiety.	NS
Core biopsy breast	3	Biopsy may be performed to alleviate patient anxiety.	NS
MRI breast with contrast	2		None
PET breast	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 9: Woman younger than 30 years of age, US findings benign (like simple cyst).

Radiologic Procedure	Rating	Comments	RRL*
Fine needle aspiration breast	2		NS
Mammography diagnostic	1		Low
US breast short interval follow-up	1		None
MRI breast with contrast	1		None
PET breast	1		High

Radiologic Procedure	Rating	Comments	RRL*
Core biopsy breast	1		NS
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 10: Woman younger than 30 years of age, US findings negative.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	5	If clinically suspicious, mammography may be appropriate.	Low
Fine needle aspiration breast	2		NS
Core biopsy breast	2		NS
US breast short interval follow-up	1		None
MRI breast with contrast	1		None
PET breast	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Breast cancer is the most common female malignancy and the second leading cause of cancer deaths in the United States. The American Cancer Society estimates that 192,370 new cases of invasive breast cancer and 62,280 new cases of in situ breast cancer will be diagnosed in 2009. A breast mass will be one of the most frequent surgical indications. A palpable breast mass may become evident during breast self-examination (BSE), clinical breast examination (CBE), or retrospectively following screening mammography.

Determining if a mass is present by physical examination can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True

masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and three-dimensional. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Benign lesions typically have discrete, well-defined margins and are mobile. Cysts cannot reliably be distinguished from solid breast masses by palpation. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examination independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant.

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions. Unfortunately, not all palpable breast masses will be visualized with conventional imaging techniques. In the Breast Cancer Detection Demonstration Project (BCDDP) begun in the 1970s, 9% of the cancers were found by CBE alone. With improvement in imaging methods since the BCDDP, this percentage should be considerably less now. Nevertheless, a negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa. Any highly suspicious breast mass detected by imaging or palpation should be biopsied unless there are exceptional clinical circumstances such as patient comorbid factors.

Mammography

Several imaging techniques are commonly used in the evaluation of palpable breast masses. Screening mammography is most useful for early detection of nonpalpable breast lesions. The examination is performed on women thought to be asymptomatic and usually consists of craniocaudal and mediolateral oblique views of each breast. A mass found with screening mammography may become perceptible by palpation after its location has been identified radiographically. Following detection of a clinical or mammographic mass, diagnostic mammography may be performed. A small metal marker is placed on the skin over the mass to identify its location. Supplemental mammographic views may be needed to clarify the features, location, or reality of a mammographic lesion. These views have been discussed extensively and include spot compression, spot compression/magnification, magnification, exaggerated craniocaudal to the medial or lateral side, tangential, change of angle, cleavage, Cleopatra, and 90-degree lateral views. Any creative nonstandard view may be used to image a lesion or move it closer to the film. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound

Ultrasound (US) was initially used only to differentiate cystic from solid lesions. Many palpable masses not visualized mammographically are cysts and can be diagnosed sonographically. With the development of 7.5 to 10 MHz linear array transducers with excellent near-field resolution, the role of US has expanded to include characterization of the shape, margins, and internal matrix of masses and guidance for needle localization, aspiration, and biopsy. US is also highly accurate

in identifying palpable malignant breast masses, although no one exam alone should be used to exclude malignancy.

Biopsy/Aspiration

Fine-needle aspiration/biopsy (FNAB) is used to remove fluid from a cyst and cellular material from a solid mass. Some physicians suggest FNAB as the first means of evaluation following physical examination, and patients with a palpable mass referred for imaging evaluation may have already undergone FNAB. Alternatively, stereotactic (X-ray) or US guidance may be used for FNAB or core biopsy if the mass is vaguely palpable, small, deep, mobile, or multiple, or if attempts using palpation to biopsy the mass have been unsuccessful. Core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses.

Multiple Modalities

The use of multiple modalities in the diagnosis of palpable masses has been advocated as a measure to increase the true positive rate. In one study comparing physical examinations, mammography, and US, the authors concluded that for palpable masses, physical examination and US formed the optimal preoperative test combination. Mammography was also necessary to detect occult cancer in the contralateral or ipsilateral breast. Diagnostic breast US can improve the specificity of clinically detected abnormalities.

The most common uses of US are characterization of palpable and mammographically depicted masses and guidance for biopsy procedures. Using strict criteria for benign and malignant features for solid masses seen on US, a high negative predictive value (99.5%) is possible to achieve. Early data suggest surveillance of solid palpable breast lesions with probably benign morphology as visualized on US, but more outcome studies are needed for confirmation. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high, over 97%. Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

Due to its lack of ionizing radiation, US is the modality of choice for evaluating a palpable mass in pregnant women. However, mammography when performed preoperatively in pregnant patients has a sensitivity of around 90%. US is also the modality of choice for evaluating palpable masses in lactating women because tissue density limits mammographic evaluation. However, mammography is not contraindicated during lactation and should be performed if malignancy is suspected, because it is particularly effective in detecting microcalcifications or subtle architectural distortion, features often not as well seen on US.

Magnetic Resonance Imaging

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a promising modality for detecting occult breast cancer and for evaluating disease extent in women diagnosed with breast cancer. The sensitivity of the examination is high,

but specificity continues to be problematic due to false positives. Although palpable masses can be imaged with MRI, it is generally more cost effective to use mammography and US as the initial imaging examinations. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than US or mammography for staging, and MRI appears to be superior to clinical examination, mammography, and US for monitoring response to neoadjuvant therapy.

Nuclear Medicine

New prospects for breast cancer detection using molecular imaging are now being actively investigated. A study comparing positron emission tomography (PET) using an isotope of glucose and single-photon-emission computed tomography (SPECT) indicates that both techniques are comparable in diagnosing breast cancer, with a sensitivity of 79% for PET and 76% for SPECT using Tc-99m methoxyisobutylisonitrile (MIBI) tracer. In another study, MIBI SPECT modified patient management in 49% of patients after a doubtful or discordant triple test with mammography, US, and FNAB. More work must be done to establish criteria for the use of nuclear medicine for breast cancer diagnosis.

Age-related Issues

Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in women younger than age 30, the imaging evaluation for patients older than age 30 differs from that performed for younger patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

In determining the utility of mammography in women younger than age 30, most researchers have retrospectively either studied patients referred for mammography or reviewed the mammographic findings of patients in whom cancer was found. In the first group of studies, as one would expect, there was a predominance of benign masses and nonspecific benign findings, although a few carcinomas were found. Most of the benign lesions were not visualized mammographically, and US was suggested as the initial imaging modality. If US demonstrates a suspicious finding, bilateral mammography is recommended to evaluate for additional ipsilateral and contralateral lesions. If US demonstrates a probably benign lesion such as a fibroadenoma in this age group, sonographic surveillance may be an acceptable alternative to traditional biopsy. In one study only 0.3% of 357 patients with such features went on to be diagnosed with malignancy. Further studies are needed. If US demonstrates a classic benign lesion such as a cyst correlating to the palpable abnormality, clinical follow-up without imaging follow-up is indicated. If US is negative, then mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically. As with women age 30 and older, most investigators agree that if physical examination is highly suspicious and mammography is negative, tissue sampling with FNAB, core biopsy, or surgical biopsy is warranted. In symptomatic young women subsequently proven to have breast cancer, mammography was abnormal preoperatively in 86% to 90% of them, suggesting that it is of substantial value in the diagnosis of malignancy.

Summary

- Because of inconsistencies in clinical examination, a thorough imaging workup of a palpable mass should be completed prior to biopsy.
- Diagnostic mammography is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman age 30 or older.
- Breast US is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman younger than age 30.
- Correlation between imaging and the palpable area of concern is essential.
- Any highly suspicious breast mass detected by imaging should be biopsied, irrespective of palpable findings.
- Any highly suspicious breast mass detected by palpation should be biopsied, irrespective of imaging findings.

Abbreviations

- MRI, magnetic resonance imaging
- NS, not specified
- PET, positron emission tomography
- US, ultrasound

Relative Radiation Level	Effective Dose Estimated Range
None	0
Minimal	<0.1 mSv
Low	0.1–1 mSv
Medium	1–10 mSv
High	10–100 mSv
*The RRL assignments for some examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc.). The RRLs for these examinations are designated as NS (not specified).	

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for the evaluation of a palpable breast mass

POTENTIAL HARMS

- Specificity of magnetic resonance imaging (MRI) continues to be problematic due to false-positive results.
- Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in women younger than age 30, the imaging evaluation for patients older than age 30 differs from that performed for younger patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made

by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Parikh JR, Bassett LW, Mahoney MC, Bailey L, Birdwell RL, Burnside ES, D'Orsi CJ, Harvey JA, Kaplan SS, Newell MS, Rabinovitch R, Rosen EL, Sutherland ML, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 10 p. [42 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Sep (revised 2009)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Jay R. Parikh, MD; Lawrence W. Bassett, MD (*Chair*); Mary C. Mahoney, MD (*Vice-Chair*); Lisa Bailey, MD; Robyn L. Birdwell, MD; Elizabeth S. Burnside, MD, MPH; Carl J. D'Orsi, MD; Jennifer A. Harvey, MD; Stuart S. Kaplan, MD; Mary S. Newell, MD; Rachel Rabinovitch, MD; Eric L. Rosen, MD; M. Linda Sutherland, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Parikh JR, Evans WP, Bassett L, Berg WA, D'Orsi C, Farria DM, Herman CR, Kaplan SS, Liberman L, Mendelson E, Edge SB, Expert Panel on Women's Imaging - Breast. Palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 4 p. [30 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#).

ACR Appropriateness Criteria® *Anytime, Anywhere*™ (PDA application). Available from the [ACR Web site](#).

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria® overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#).
- ACR Appropriateness Criteria® literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the [ACR Web site](#).
- ACR Appropriateness Criteria® evidence table development. Reston (VA): American College of Radiology; 4 p. Electronic copies: Available in Portable Document Format (PDF) from the [ACR Web site](#).
- ACR Appropriateness Criteria® radiation dose assessment introduction. American College of Radiology. 2 p. Electronic copies: Available from the [ACR Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer on September 9, 1999. The NGC summary was updated on November 12, 2004. The information was verified by the guideline developer on December 21, 2004. This NGC summary was updated by ECRI Institute on May 17, 2007 and on May 12, 2010.

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